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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,663	08/31/2005	Shizuo Akira	31671-211618	1905

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EXAMINER	
DOWELL, PAUL THOMAS	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/517,663	AKIRA, SHIZUO	
	Examiner	Art Unit	
	Paul Dowell	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, drawn to a non-human animal model non-responsive to mycobacterial lipoproteins/lipopeptides, wherein the function of the gene encoding a protein specifically recognizing mycobacterial lipoproteins/lipopeptides is deleted on its chromosome.

Group II, claim(s) 8 and 10-13, drawn to a method for screening substances promoting or suppressing the response to mycobacterial lipoproteins/lipopeptides, wherein the response to mycobacterial lipoproteins/lipopeptides in the immunocytes derived from a non-human animal model non-responsive to mycobacterial lipoproteins/lipopeptides is measured/estimated by using the immunocytes, a test substance and a mycobacterial lipoprotein/lipopeptide.

Group III, claim(s) 9, drawn to a method for screening substances promoting or suppressing the response to mycobacterial lipoproteins/lipopeptides, wherein the response to mycobacterial lipoproteins/lipopeptides of a non-human animal model non-responsive to mycobacterial lipoproteins/lipopeptides is measured/estimated by using

the non-human animal model, a test substance and a mycobacterial lipoprotein/lipopeptide..

Group IV, claim(s) 14-17, drawn to a substance promoting or suppressing the response to mycobacterial lipoproteins/lipopeptides.

Group V, claim(s) 18 and 19, drawn to a therapeutic/preventive agent for mycobacterial infection containing TLR1 and TLR2 expression systems.

Upon election of any one of groups II, III, IV or V, Applicant is required to make the following additional elections:

1) Upon election of groups II, III or IV, Applicant is required to elect either promoting or suppressing the response to mycobacterial lipoproteins/lipopeptides as the goal of the screening methods of groups II and III as recited in claims 8, 10, 11, 12 and 13 (for group II) and as recited in claim 9 (for group III) and;

Applicant is required to elect either a substance that promotes or a substance that suppresses the response to mycobacterial lipoproteins/lipopeptides as recited in claims 14-17 (for group IV).

2) Upon election of group II or IV, Applicant is required to elect either an agonist or antagonist as recited in claims 11 (for group II) and 15 (for group IV).

3) Upon election of group II, IV or V, Applicant is required to elect either a mycobacterial infection that is tuberculous or a mycobacterial infection other than tuberculous as recited in claims 13 (for group II) and 17 (for group IV) and 19 (for group V).

It is noted that these are restrictions and not species elections since: promoting and suppressing the response to mycobacterial lipoproteins/lipopeptides are distinct and opposite actions that are mediated by distinct agents and that occur through distinct modes of action and agonists and antagonists are structurally and functionally distinct agents that mediate opposite effects through distinct modes of action.

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The technical feature of group I appears to be a non-human animal model non-responsive to mycobacterial lipoproteins/lipopeptides, wherein the function of the gene encoding a protein specifically recognizing mycobacterial lipoproteins/lipopeptides is deleted on its chromosome. However, said technical feature is taught by Takeuchi et al **(International Immunopharmacology, 1:625-635, 2001)** to lack novelty or inventive step because Takeuchi teaches a toll-like receptor 2 (TLR2) knockout mouse (page 628, col. 1, paragr. 2, last 3 lines) and Takeuchi teaches that TLR2 recognizes bacterial lipoproteins (Abstract, lines 4-5). Further, while groups I-IV contain said technical feature, group V does not share said technical feature. Therefore, the instant technical feature of groups I-IV does not make a contribution over the prior art and group V does not share said technical feature.

Furthermore, groups I, IV and V are patentably distinct each from the other because they are drawn to distinct products. For example, group I is drawn to non-human animal model, while group IV is drawn to a substance that promotes or suppresses the response to mycobacterial lipoproteins/lipopeptides, while group V is drawn to a therapeutic agent for mycobacterial infection containing TLR1 and TLR2 expression systems. The non-human animal model of group I, the substance of group IV and the therapeutic agent of group V are products with distinct structure, function and mode of action.

Furthermore, while groups II and III are related in being drawn to methods for screening substances promoting or suppressing the response to mycobacterial lipoproteins/lipopeptides, they are patentably distinct because they are drawn to methods with distinct starting materials. For example, the method of group II requires a non-human animal model non-responsive to mycobacterial lipoproteins/lipopeptides while the method of group III requires immunocytes obtained from a non-human animal model non-responsive to mycobacterial lipoproteins/lipopeptides. Said non-human animal model and cells obtained from said non-human animal model are structurally and functionally distinct products that represent distinct starting materials for the methods of groups II and III.

Furthermore, group I is related to groups II, III as product (group I) and process of use (groups II, III). The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the non-human animal model of group I can be used in the materially different processes of groups II and III. Specifically, the non-human animal model of group I can be used directly in the screening method of group III and can be used indirectly as a source of immunocytes in the screening method of group II.

Furthermore, groups II, III are unrelated each to groups IV, V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and §

806.06). In the instant case, the different inventions are not disclosed as capable of use together.

A search and examination of more than one invention as defined above would unduly burden the Office. Each of the inventions requires a different search of the art and concerns separate considerations of patentability. For example, the subject matter of many of the inventions is not largely co-extensive as the inventions are related to distinct products and methods. Therefore, restriction as defined above is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Dowell whose telephone number is (571)272-5540. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Dowell
Art Unit 1632

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER